HEART HEALTH:

Cardiovascular Guidelines for Community Health Centers

TRAINING REFERENCE MANUAL

JUNE 2010

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CHCANYS | *Defining New Directions*
Community Health Care Association of New York State

ACKNOWLEDGEMENTS

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ACRONYMS

The following acronyms are used throughout. Please use this reference page while reviewing manual templates.

CHCANYS — Community Health Care Association of New York State

CLIA — Clinical Laboratory Improvement Amendments

CPT — Current Procedural Terminology

CSTI — Clinical Staff Training Institute

CVD — Cardiovascular Disease

FDA — U.S. Food and Drug Administration

FQHC — Federally Qualified Health Center

HbA1c — Hemoglobin A1c

HDL — High-density lipoprotein

HRHCare — Hudson River HealthCare, Inc

ICD-9 CM — International Classification of Diseases, Ninth Revision, Clinical Modification

LDL — Low-density lipoprotein

LPN — Licensed Practical Nurses

NYS DOH CLEP — New York State Department of Health's Clinical Laboratory Evaluation Program

NYS DOH HHP — New York State Department of Health's Healthy Heart Program

PECS — Patient Electronic Care System

POCT — Point-of-Care Testing

PPM — Provider Performed Microscopy

PTS — Polymer Technology Systems, Inc.

RN — Registered Nurse

FORWARD

Dear Colleague,

The Community Health Care Association of New York State (CHCANYS) would like to share the training reference manual, *Heart Health: Cardiovascular Guidelines for Community Health Centers,* with you and your affiliated community health centers.

The intended outcome of this training reference manual is to provide institutions, such as Federally Qualified Health Centers (FQHCs), with guidelines that address transitioning, developing and sustaining organizational strategy and policy to improve cardiovascular patient care. Specifically, this manual should be used to:

- Educate clinical staff about potential errors, factors and techniques that lead to blood measurement inaccuracy; and,
- Review appropriate Clinical Laboratory Improvement Amendments (CLIA) Waived Point-of-Care requirements and procedures required to establish and implement a sustainable testing system for cardiovascular disease.

We hope you will find this resource a valuable training tool that will assist your institution in improving cardiovascular patient care.

By working together, CHCANYS hopes to further address issues that New York State FQHCs face when caring for hypertensive patients.

For more information about this resource, please contact CHCANYS Quality Initiatives via telephone at 212-279-9686. Thank you.

Sincerely,

Elizabeth H. Swain
Chief Executive Officer
Community Health Care Association of New York State

CHCANYS

Established in 1971, CHCANYS is the voice for community, migrant and homeless health centers as leading providers of patient-centered primary care in New York State. Recognized as a strong and effective primary care association by national peers and the federal government, CHCANYS is the "go-to" organization in New York State for guidance and analysis on community health policy and regulatory reform. The success and strength of our collaborations has made CHCANYS a pivotal partner for policy makers and community-based organizations wanting a stronger primary and prevention-based system.

As a not-for-profit statewide association, CHCANYS works to:

- Increase access to health care for uninsured and underinsured people through a program of health policy leadership, regulatory reform, and grassroots advocacy;
- Support community health centers with tools and information necessary to maintain and improve existing programs, strengthen core services and build new programs;
- Enhance workforce development and best practice service delivery through clinical initiatives, workshops and conferences; and,
- Implement health information technology in health centers across the state, with a focus on the adoption of electronic health records and the development of reporting tools for clinical decision making.

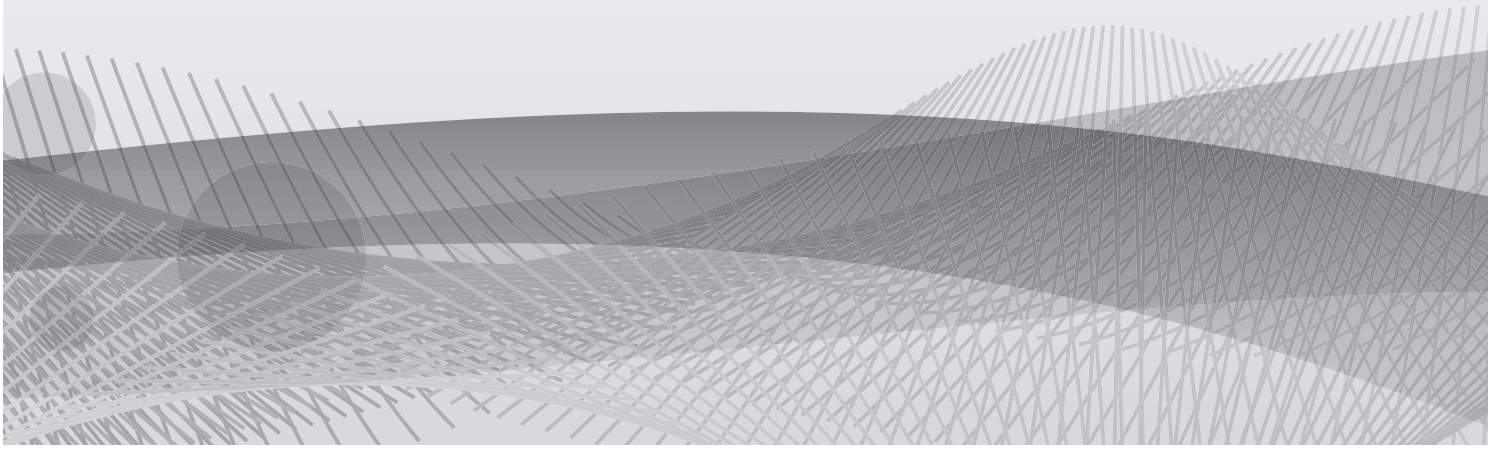
CHCANYS' purpose is to ensure that the medically underserved living in New York State have continuous access to quality community-based health care services and that all New Yorkers have a primary care home. To do this, CHCANYS serves as the voice of community health centers as leading providers of primary health care in New York State. CHCANYS supports universal access to health care and coverage for all New Yorkers.

BACKGROUND

On a national level, FQHCs, agencies and organizations are examining the accuracy of blood pressure measurement and Low-density Lipoprotein (LDL) Point-of-Care Testing (POCT). The risks of inaccurate blood pressure measurement and LDL POCT both have the potential for harm. Either can lead to under or over treating patients. This training reference manual is meant to provide FQHCs with guidelines in standardizing blood pressure measurement procedure and CLIA Waived POCT. The blood pressure component of this manual centers around the experiences, best practices and recommendations of HRHCare. Procedures regarding CLIA Waived Point-of-Care are based on standards set by the Joint Commission.

PART ONE:

Measuring Blood Pressure Accurately



MEASURING BLOOD PRESSURE ACCURATELY

CASE STUDY: HUDSON RIVER HEALTHCARE, INC.

HRHCare is a network of sixteen community health center sites in six counties located in the lower Hudson Valley and Long Island regions within New York State. HRHCare is an FQHC and is accredited by the Joint Commission for primary care and behavioral health. Its mission is to increase access to comprehensive primary and preventive health care and to improve the health status of its surrounding community, especially for the underserved and vulnerable. HRHCare operates under the Care Model, formerly known as the Chronic Care Model.

In 2006, several HRHCare providers expressed concern about the accuracy of blood pressure readings. Blood pressures recorded on the Patient Electronic Care System (PECS) were found to be too consistent with previous readings, which alerted HRHCare providers to a possible concern. Providers and Nurse Managers also noticed documented incorrect blood pressure readings due to: incorrect cuff sizes attached to the sphygmomanometers used on patients having their blood pressure assessed; and cuffs not deflating or holding air properly. This increased the risk for inaccurate readings.

HRHCare made a decision to address the accuracy of blood pressure measurement by creating nursing skill competencies for their nursing staff. The strategies they used include the following: (1) developing protocols that address the proper use of equipment; and (2) providing training to nursing staff in the proper methods for assessing blood pressure.

FACTORS TO CONSIDER FOR ACCURATE BLOOD PRESSURE MEASUREMENT

THE OBSERVER

Inaccurate blood pressure reading can result from numerous interdependent factors. These include the use of malfunctioning or inappropriate equipment and incorrect measurements. When assessing blood pressure, the most fallible factor is the ***observer.*** Because nursing or clinical staff are the observers when measuring and documenting patient's vital signs, they play a significant role in the accuracy of the measurement. FQHCs cannot solely rely on the background training of their nursing staff, which may consist of certificate programs or nursing degree programs. Clinical leadership should not assume ongoing staff competency in essential skills. When accounting for the observer factor, it is important for clinical leadership at health centers to ask the following questions:

- How do we, as a community health center, assess competencies such as blood pressure measurement in our staff?
- As any other nursing skill, should we assess blood pressure as a core competency?

TRAINING

HRHCare believed that if all staff understood the importance of accurately measuring blood pressure they would utilize the skills learned in training and therefore increase the accuracy of their results. They reviewed how staff was trained and addressed blood pressure accuracy concerns by: (1) creating protocols that increased nursing staff awareness of accurate blood pressure measurement with a focus on equipment; and (2) providing training to nursing staff in the proper methods for assessing blood pressure. HRHCare also surveyed its staff members to gather information about their educational backgrounds. The results of the survey showed that its staff was trained through a variety of methods, such as: on the job training, training programs, nursing assistant certificate programs; or Registered Nurse (RN) or Licensed Practical Nurses (LPN) status. The information was used to create a process for addressing staff training based on measureable goals.

EQUIPMENT

Equipment is another important component that should be considered if a health center wants to ensure that blood pressure measurements are accurately taken. Functional blood pressure cuffs, sphygmomanometers and stethoscopes are necessary to obtain accurate blood pressure measurements. Health centers can designate their Nurse Managers or trained staff members to conduct frequent environmental checks of their exam rooms to ensure proper functioning equipment.

CREATING AN ORGANIZATIONAL POLICY TO ENSURE BLOOD PRESSURE ACCURACY

The HRHCare senior staff used their organization's existing team approach by creating an internal team to assess staff training needs and design protocols. Their team included the Director of Staff Education, Director of Nursing, Vice President of Human Resources, Quality Improvement Coordinator and Director of Health Collaboratives. Selection of the team members was based on skill set and educational background rather than positions at the health center.

The HRHCare team presented its findings on the ways the health center could further ensure blood pressure accuracy and improve overall patient care to its leadership. The new blood pressure accuracy component was included in its mandatory annual education program for nursing staff. The health center's administration provided financial support for the purchase of new training equipment and staff time needed for training instructors and participants. The following training tools were purchased as part of this initiative: blood pressure training arms; new blood pressure cuffs to replace any defective cuffs; and double stethoscopes for training evaluation. In addition, competency tools were developed, tested and retested. The Nursing and Human Resources policies reflected revised competencies required for each position. These would be included in corresponding job descriptions and annual performance reviews. New policies were also created to provide guidance on how to work with a staff member who may be unable to meet the competency requirements.

KEY COMPONENTS NEEDED FOR ACCURATE BLOOD PRESSURE MONITORING

EQUIPMENT

Some of the reasons for error could be faulty equipment. Sphygmomanometers need to be checked every 6 months and calibrated per manufacturer's recommendations. Nurse Managers should immediately be made aware of any blood pressure cuffs that are torn or those that do not hold air properly. Damaged or defective equipment should be replaced. This includes outdated or damaged stethoscopes. Multiple sized blood pressure cuffs should be housed in each exam room.

A useful resource to consult when considering the purchase of blood pressure equipment is the dabl®Educational Trust: http://www.dableducational.org/index.html. Information provided by the dabl®Educational Trust is free of commercial or product bias and can be used to assist in evaluating the range of blood pressure equipment available for purchase in today's current market.

SKILLS AND TRAINING

Health center support staff must be trained on how to measure blood pressure accurately. In addition to demonstrating skills to properly assess blood pressure, staff must also understand that abnormal results should be handled as per the health center's clinical policy and procedures. Staff also needs to understand how patient behavior and patient positioning can affect results. For example, Exhibit 1 highlights errors that can occur when a patient's blood pressure is taken.

PATIENT PREPARATION

The waiting time from the time the patient enters the room until the blood pressure is measured should be 3 to 5 minutes. Staff should be encouraged to assess the reason for visit and other vital signs prior to blood pressure measurement. It should be noted that blood pressure readings are affected by the following:

- Cold exposure: increase 11/8 mmHg
- Full bladder/bowel: increase 27/22 mmHg
- Physical activity: decrease 5-11/4-8 mmHg
- Smoking: increase 10/8 mmHg
- Stimulants: increase 8-10/7-8 mmHg

STANDARDIZATION OF PROPER PATIENT POSITIONING

Patients should be seated in the upright position in a chair with their backs supported and feet flat on the ground. They must be positioned so that the sphygmomanometer is clearly visualized by the nurse.

LIMB SELECTION

Organizational policy regarding the accuracy of blood pressure measurement should indicate that blood pressure should be taken on both arms during a patient's first visit at the health center, unless contraindicated due to AV fistula, disease or injury, or mastectomy. Right or left arm preference or limitations should be documented in the chart. It should be noted that the Joint Commission recommends two readings two minutes apart.

CUFF AND STETHOSCOPE PLACEMENT

The cuff should be positioned with the center of bladder approximately 1 inch above the patient's brachial artery. The cuff should fit the arm correctly as per cuff markings, or refer to Exhibit 2 for proper measurements. Clothing should not be allowed to create constriction in the upper arm area. A concept of "barearm" for blood pressure measurement is recommended. The arm should be supported at heart level with the palm facing upward.

EXHIBIT 1

This picture depicted as Exhibit 1, illustrates various situations that may result in inaccurate blood pressure readings. These include the following:

- Patient and or staff speaking during the blood pressure assessment;
- Patient consuming coffee prior to and/or during the blood pressure assessment;
- Patient sitting with unsupported feet, back and arm(s) during the reading;
- Patient sitting with crossed feet;
- Patient having a fully clothed arm; and,
- Medical equipment improperly placed, including the wrapping of cords around the patient's arm.

EXHIBIT 2

ACCEPTABLE BLADDER DIMENSION FOR ARMS OF DIFFERENT SIZES

CUFF	BLADDER WIDTH (cm)	BLADDER LENGTH (cm)	ARM CIRCUMFERENCE RANGE AT MIDPOINT (cm)
Newborn	3	6	< 6
Infant	5	15	6-15+
Child	8	21	16-21+
Small Adult	10	24	22-26
Adult	13	30	27-34
Large Adult	16	38	35-44
Adult Thigh	20	42	45-52

INFLATING THE BLOOD PRESSURE CUFF

The two methodologies that are generally accepted are: (1) review the last blood pressure and add 30 mmHg; and (2) determine the palpatory systolic pressure and add 30 mmHg. The common practice of inflating the cuff to 180 mmHg to 200 mmHg should be discouraged. The following procedure for determining the palapatory systolic pressure is recommended:

1. Apply blood pressure cuff to the arm and palpate brachial pulse;
2. While continuing to palpate the brachial pulse, inflate the blood pressure cuff until the pulse is no longer felt;
3. Slowly release the valve at 2 to 3 mmHg/sec; and,
4. Record when pulse is felt again. (That is the palpatory systolic pressure.)

OBTAINING THE PATIENT'S BLOOD PRESSURE RESULT

Health centers need to determine whether or not to use the bell or diaphragm of the stethoscope for measuring blood pressure. HRHCare uses the diaphragm portion of the stethoscope to obtain its readings. The following protocol is recommended:

- Staff must objectively assess and document blood pressure readings, even when it appears out of the patient's usual range.
- Blood pressure reading should be recorded to the nearest "two" (e.g., 0, 2, 4, 6, and 8).
- Talking or similar interruptions should not occur during the blood pressure measurement procedure as this will skew the reading results.
- Once the cuff is inflated and the stethoscope is in position, the staff should slowly release the pressure bulb valve at a rate of 2 mmHg/second.
- The first two Korotkoff consecutive sounds is the systolic reading and the fifth Korotkoff sound is the diastolic reading. Tutorials are extremely helpful in teaching this concept. Listening and understanding Korotkoff sounds are areas that need significant reinforcement during training. Korotkoff sounds may be hard to hear initially.
- If problems arise, the cuff should be deflated completely and the measurement redone after one to two minutes. There should be no restarting in the middle of obtaining a reading.
- Standard stethoscopes should be used. Measurement can vary with different stethoscopes.

STAFF TRAINING AND COMPETENCY

STRATEGIES TO DEVELOP A BLOOD PRESSURE TRAINING AND COMPETENCY

As discussed, HRHCare developed several strategies to educate and train staff. The following are some strategies that your health center may want to adopt:

- Implementation of an orientation process for new employees that guarantees competencies in assessing vital signs and other in-office procedures, that have measurable outcomes and utilize training tools such as online blood pressure training tutorial(s), blood pressure training arm(s) and blood pressure measurement verification with a training double stethoscope;
- Reinforcement of training for present employees;
- Development of an annual and mandatory training program; and,
- Routinely adding problem solving on the agenda during site staff meetings.

STEPS TO IMPLEMENTING THE TRAINING

One of the most important steps in staff training is the creation of an orientation training program tailored to the health center staff needs. It is recommended that health center leadership organize an orientation program task force with the following responsibilities:

- Assess staff experience and knowledge utilizing appropriate surveys;
- Create competency checklists that align with current standards;
- Develop staff competency assessment tools;
- Review different types of tutorials and training tools for use during the orientation program; and,
- Determine how to objectively evaluate competency standards for all employees who undergo the orientation or training process.

HRHCare recommends that the result the staff member obtains must be within 4 mmHg of the correct reading to be considered competent. Training participants undergo a tutorial and then complete five to six readings. Staff members visit various stations and must use the blood pressure training arm to check the blood pressure. If there are problems accomplishing these outcomes, the participant is asked to take an instructor's blood pressure using the double stethoscope. If unable to obtain a reading within an acceptable range, the staff member will be referred to the Nurse Manager to assist with remediation and will not be allowed to take patients' blood pressures until competency is obtained. If problems with hearing are suspected, an audiology referral for evaluation is discussed with the staff member.

An excellent training resource is the following tutorial from the British Hypertension Society: http://www.abdn.ac.uk/medical/bhs/index. This interactive tutorial describes many of the key components for accurate blood pressure assessment. These include patient positioning, cuff placement and sizing. It provides exercises where the tutorial user can: listen to the drop in mercury; hear the different Korotkoff sounds; and determine a blood pressure reading. After the exercises are completed, the tutorial provides the user with feedback to the answers chosen, correct answers and informative comments. The program will take several minutes to download. External speakers or headsets may be helpful. There is no cost to obtain the tutorial.

HUDSON RIVER HEALTHCARE'S CLINICAL STAFF TRAINING INSTITUTE

In reference to the case study, HRHCare created the Planetree Clinical Staff Training Institute (CSTI). Attendance is yearly and mandatory for all nursing employees. The Planetree CSTI is a secure and confidential learning environment for implementing training orientation with measurable outcomes. The following is a summary of the institute's development.

2007: HRHCare created a full day training program for LPNs, RNs and Clinical Assistants. The program was held on Saturdays to: ensure access to an appropriate number of clinic rooms; not interrupt health center services; and provide a focused environment for training participants. The initial training focused on scope of practice issues and essential skills and competencies regarding blood pressure measurement accuracy. CSTI also allowed HRHCare to review competencies around the following: vital signs; review of asthma and use of nebulizers/peak flow meter; review of diabetes and home glucose monitoring/insulin teaching; hypertension patient education components; and blood pressure competency.

Sessions were assigned based on participants' scope of practice (i.e., Nurse or Clinical Assistant). The didactic methodologies used were lecture, discussion, pre- and post- tests, and demonstration of skills (i.e., blood pressure, insulin administration and fingerstick blood for glucometer). Evaluation of training participants was positive but feedback stated that there was too much information covered during the training. Based on HRHCare's evaluation, it was noted that it needed to put more emphasis on continued blood pressure training (e.g., incorrect numbers as noted with teaching stethoscope, improper cuff placement and choice of cuff, and limited knowledge in factors associated with improper readings).

2008: HRHCare took the opportunity to adjust its training based on feedback and lessons learned from 2007. Based on this assessment, future trainings were changed to half day sessions and would be implemented on weekdays to avoid staff overtime. The training program was also changed to be more didactic rather than classroom based. An emphasis was placed on blood pressure measurement, as this remained an issue after reviewing training assessments and preference was for practice-based demonstrations. HRHCare created a protocol to deal with staff that was unable to demonstrate proper competency skills. If a staff member was unable to complete a return demonstration correctly after 3 attempts, the staff member was referred to the Nurse Manager for further remediation and evaluation. During the period of remediation, the staff member would not be allowed to perform blood pressure measurements in service until competency was achieved. Evaluations were kept confidential at all times.

2009: Based on 2008 findings, HRHCare incorporated lab competencies into its training program. Due to this change, the program went back to full day sessions but focused on either nurses (i.e., RN and LPN) or Clinical Assistants. Training staff on blood pressure competencies continued to be addressed through the use of tutorial and included practice sessions with an automated arm. HRHCare adopted institutional policies to address situations where the objective standards of practice were not met. Policy and procedures included a remediation process, documentation of results and correlation with human resources job performance policies.

2010: HRHCare currently uses the developed protocols and procedures and continues to re-evaluate and refine its training program. It reviews and updates CSTI by using the PDSA process to test new ideas and to involve Nurse Managers. Site visits occur on a bi-monthly basis to discuss training results. Open dialogue is encouraged and evaluations are distributed for feedback.

OUTCOMES AND BENEFITS OF THE PROGRAM

Health centers that implement employee competency training programs can ensure their providers that the clinical staff has obtained accurate blood pressure readings for its patients. Training programs increase staff satisfaction and decrease staff turnover, which can save money on additional training and the recruitment process for new personnel. As with all health centers interested in improving care, quality improvement should be the main goal.

BLOOD PRESSURE MEASUREMENT TEMPLATES

- Blood Pressure Measurement Proficiency Testing Log
- Competency Checklist for Blood Pressure Measurement

BLOOD PRESSURE MEASUREMENT PROFICIENCY TESTING LOG

EMPLOYEE NAME/TITLE: _____

TRAINER NAME: _____

DIRECTIONS: The procedure must be followed as specified on the blood pressure competency checklist. The blood pressure readings must be within plus or minus 4 mm Hg of the tutorial/trainer for 4 out of 6 readings of K1, K4 and/or K5 for each of the learning sessions.

BRITISH HYPERTENSION SOCIETY VIDEO TUTORIAL

Date: _____

TUTORIAL READING	STAFF READING	SUCCESSFUL	UNSUCCESSFUL	COMMENT

Level of accuracy ____/____

PROFICIENCY ACHIEVED (circle one): MET NOT MET

Corrective action plan (if not met):

_____

_____

_____

BLOOD PRESSURE SIMULATOR

Date: _____

SIMULATOR READING	STAFF READING	SUCCESSFUL	UNSUCCESSFUL	COMMENT

Level of accuracy ____/____%

PROFICIENCY ACHIEVED (CIRCLE ONE): MET NOT MET

Corrective action plan (if not met):

_____

_____

_____

_____

COMPETENCY CHECKLIST FOR BLOOD PRESSURE MEASUREMENT

EMPLOYEE NAME/ TITLE: _____

DATE: _____

TRAINER NAME: _____

Competency is validated by (simulated) observation, oral discussion and/or return demonstration.

Prerequisite: View "Blood Pressure Measurement" Video/British Hypertension Society Tutorial
Blood pressure measurement is an important indicator of the current clinical condition of patients and a powerful predictor of future cardiovascular overall health.

Source: "The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure" (1997)

TASK	SATISFACTORY	UNSATISFACTORY
Gather equipment: stethoscope, calibrated sphygmomanometer, tape measure, chair and blood pressure cuff.		
Explain procedure to patient.		
Patient needs to be resting approximately 5 minutes before measurement.		
Identifies conditions or factors for blood pressure variation.		
Position patient with feet on floor, legs uncrossed and their back supported.		
Expose the patient's arm at least 5 inches above the elbow: sleeve can be rolled up but observer must be able to fit finger under it, or it should be removed		
Assess for correct size cuff. The bladder should encircle and cover two-thirds of the width of the arm: squeeze all air out of cuff before applying to patient.		
Arm is supported, at patient's heart level, palm turned up.		
Place cuff on bare arm. The center of the bladder should be positioned over the line of the artery. The lower edge of the bladder should be 2-3 cm (1 inch) above the marked point.		

Continued...

TASK	SATISFACTORY	UNSATISFACTORY
Determine the palpatory systolic pressure by palpating for the brachial/radial artery, closing the valve, and inflatingthe cuff. When the pulse is no longer felt, this is the palpatory pressure. This is your palpatory systolic pressure; recall this number. Release the air from the cuff, and wait 30 seconds.		
Add 30 mmHg to the palpatory systolic pressure. This will be your starting point for blood pressure measurement.		
Check stethoscope amplification for sound.		
Position the diaphragm of the stethoscope over the brachial pulse.		
Close the valve on the bulb and inflate the cuff to the appropriate reading on the manometer.		
Deflate at 2 mmHg/heartbeat (second).		
When the first 2 consecutive sounds are heard, note the reading on the manometer. This is the systolic pressure. Continue to allow air to escape and watch the manometer/ needle gauge.		
At the absence of any more sounds, note the reading on the manometer. This is the diastolic pressure.		
Allow for an additional 10 mmHg to be released slowly ensuring there are no further sounds. Release the remaining air in the cuff by opening the valve completely and remove the cuff.		
If there is a need to re-inflate to check for accuracy, completely deflate, wait 1-2 minutes and then re-inflate.		
Document in patient record, patient position, arm used, cuff size, blood pressure measurement to the nearest 2 mmHg, and any deviations from measurement protocol that were unavoidable.		

Continued...

COMPETENCY ACHIEVED (circle one): MET NOT MET

CORRECTIVE ACTION PLAN (if not met):

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____ _____

Staff Member Signature Date

_____ _____

Reviewer Signature Date

* Determine if the patient has any contraindications that limit the arm on which the blood pressure is taken. These may include an intravenous line, mastectomy, wounds, an AV shunt, swelling, pain, or deformities. Do not take the blood pressure in an arm with any of these problems. Both clinician/observer and patient should be quiet while blood pressure is being assessed.

*<u>One step-method:</u> observer will appropriately inflate cuff as per appropriate procedure.

Please refer to the "Inflating the Blood Pressure Cuff" section of this training reference manual

CLASSIFICATION OF BLOOD PRESSURE LEVEL IN ADULTS	SYSTOLIC mmHg	DIASTOLIC mmHg
Normal	<120	<80
Pre-hypertension	120-139	80-89
Stage 1 Hypertension	140-159	90-99
Stage 2 Hypertension	160 or >	100 or >

**American Heart Association and National Heart, Lung, and Blood Institute categories*

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PART TWO:

In-House CLIA Waived Point-of-Care Diagnostic Testing

IN-HOUSE CLIA WAIVED POINT-OF-CARE DIAGNOSTIC TESTING

INTRODUCTION

All laboratory testing was traditionally performed in a central laboratory by staff specifically educated in laboratory science and medicine. Technological advancement has moved laboratory testing to the patient's bedside, physician's office, and other non-laboratory settings. POCT provides results in real time to the provider during the patient visit. The provider and patient can discuss the results and determine the best course for their treatment, thus increasing the compliance of the patient.

Many POCT systems and analytes are CLIA Waived. CLIA Waived test devices do not have specific personnel requirements for performing the tests. There are no personnel requirements, but there are requirements for performing the tests in any setting. It is important to determine if the CLIA Waived Point-of-Care test you have selected is appropriate for your facility and setting. A clear and comprehensive understanding of the State licensing requirements, selecting a quality test system, competency training, documentation of results, and establishing written policies and procedures are essential for implementing a successful CLIA Waived POCT Program.

Competency assessment for a CLIA Waived Point-of-Care test system for treating and monitoring Cardiovascular Disease (CVD) begins with the test system selected by your facility. If the test system is not a quality system, the results obtained will not be accurate. This can be costly to your organization. Cost savings that may have been made available through quantity purchasing may be lost due to the poor quality of the test system selected.

Competency assessment is a crucial element for the personnel performing the CLIA Waived Point-of-Care Test system. There are no specific educational requirements for the personnel performing these tests. The staff must demonstrate they have a clear and comprehensive understanding of the test system, quality control requirements, and recognizing when an error has occurred in the test system. Their competency is essential for providing accurate and correct results to the provider.

The guidelines provided in the following section will help you to establish and implement a competency assessment curriculum for a quality CLIA Waived Point-of-Care test system for CVD.

CLINICAL LABORATORY IMPROVEMENT AMENDMENT

Congress enacted CLIA in 1988 to establish "quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient results regardless of where the test was performed."

Current law states that all laboratories must be certified under CLIA to perform testing on human specimens. CLIA regulations define a laboratory as *"a facility for the …examination of materials derived from the human body for the prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body."*

Congratulations, you are a laboratory! It is not a specific room or site, but what and where you are performing and reporting.

NEW YORK STATE LIMITED SERVICE LABORATORY REGISTRATION

The New York State Department of Health's Clinical Laboratory Evaluation Program (NYS DOH CLEP) provides oversight to facilities performing waived and/or provider performed microscopy procedures in New York State. New York State identifies the facilities as Limited Service Laboratories. The facilities must register with the Department to obtain a CLIA number and become authorized to perform patient testing. A registration packet will be provided to the facility upon notification to the Department that the facility will provide patient testing on site. There is a $200.00 fee that must accompany your registration packet.

Contact the NYS DOH CLEP at:
New York State Department of Health
Wadsworth Center
Clinical Laboratory Evaluation Program
P.O. Box 509
Albany, New York 12201-0509
Telephone: (518)402–4253
Fax: (518)485–5414
Email: cleptd@health.state.ny.us
www.wadsworth.org/labcert

An initial CLIA registration number will be issued when the application is approved. Registrations are valid for two years from the date of issue. Registrants may only perform the tests listed on the State approved documents.

BEFORE INTRODUCING WAIVED TEST SYSTEMS OR OFFERING A NEW WAIVED TEST SYSTEM

A considerable amount of planning and preparation is essential to implementing a quality waived testing program.

THINGS TO CONSIDER

- **MANAGEMENT RESPONSIBILITY FOR TESTING:** Determine who will be responsible and accountable for the waived and/or Provider Performed Microscopy (PPM) testing oversight at each facility; determine if the person is qualified for supervising and making decisions on testing.
- **REGULATORY REQUIREMENTS:** Be knowledgeable of all federal, state, local and regulatory agencies regulations that apply to waived and/or PPM testing.
- **SAFETY:** Understand the safety requirements for testing personnel and patients.
- **TESTING SPACE AND FACILITIES:** Provide adequate space for testing that meets all regulatory requirements
- **STAFFING:** Understand clinic needs, including staffing, work flow and training needs.
- **BENEFITS AND COSTS:** Evaluate the benefits of adding in-house lab testing for patient care and perform a cost analysis.
- **DOCUMENTATION AND RECORDS:** Ensure a system for proper documentation and record keeping.

EVALUATION OF PROPOSED CLIA WAIVED POINT-OF-CARE TEST SYSTEM

- **PURPOSE:** Why perform in-house tests instead of sending specimens to a reference laboratory?
- **VOLUME:** Low volume may compromise the competency of personnel and reagents may expire before being used, making the in-house testing not cost effective.
- **METHODOLOGY:** What methodology is used for each analyte? Is the method reasonable for the purpose?
  - a) Sensitivity
  - b) Specificity
  - c) Precision
  - d) Batch versus discrete technology
  - e) Reagent and control stability
  - f) Reagent and control storage requirements
  - g) Quality Control requirements

• **COST OF THE METHOD:** In-House CLIA Waived POCT does not solely revolve around the cost of an individual test versus the cost of a reference laboratory testing method. The cost of program implementation has implications on the whole process of patient care. An in-house test can provide results in less than six minutes; thus, providing a test result before the patient leaves the office. Items to be considered:

a) Cost of training the staff and maintaining competency

b) Cost of labor associated with processing and analyzing the specimen

c) Cost of labor associated with maintaining the equipment

d) Annual reagent, control, maintenance and depreciation costs

e) Cost of state licensing, according to volume and test complexity

f) Cost of proficiency programs for testing performed

g) Volume of use versus maintenance of equipment

WAIVED TEST REQUIREMENTS

A Certificate of Waiver is issued to facilities performing specific in-house laboratory testing that is approved by the U.S. Food and Drug Administration (FDA) for the Waived tests category. A Waived Test must be:

- Approved by FDA for home use
- Determined to have an insignificant risk of erroneous result, including those that:
  - ➢ "Are so simple and accurate as to render the likelihood of erroneous results negligible; or
  - ➢ The Secretary has determined no posed reasonable risk or harm to the patient if performed incorrectly."
- Follow manufacturer's instructions for Waived Tests and to limit testing methods to those that are approved by the FDA as waived.

VULNERABILITY CONCERNS FOR WAIVED TESTS

- Failure to follow manufacturer's instructions
- Failure to identify incorrect results
- Testing beyond the laboratory's CLIA certificate
- Untrained staff
- Lack of quality control
- Poor equipment
- Poor storage of results
- Poor recordkeeping
- Misunderstanding of requirements

JOINT COMMISSION ACCREDITATION FOR WAIVED TESTING REQUIREMENTS

The following must be established and implemented to meet Joint Commission requirements:

1. Evaluate Waived Testing during inspection process
2. Test method/performance verification for accuracy/precision/reference range
3. Quality control
4. Specific education requirement for POCT
5. Personnel training
6. Identify testing and supervisory personnel for POCT
7. Document initial and annual competency skills
8. Performance appraisal process
9. Continuous quality improvement/Total Quality Management program
10. Written Standard Operating Procedure for:
    - **a**) Specimen collection and preservation
    - **b**) Quality control
    - **c**) Equipment performance maintenance
    - **d**) Instrument calibration
    - **e**) Problem and remedial action
    - **f**) Test performance
11. Annual review of Standard Operating Procedure by Director and/or Supervisor of Testing and Laboratory
12. Patient test result reporting
13. Audit trail linking test results to analyst to quality control and to instrument problem
14. Correlation of test results across different instruments and different sites (semiannual)
15. Evidence to support that quality and stability of reagents are monitored

NYSDOH CLEP monitors CLIA Waived Point-of-Care Tests according to the same requirements as the Joint Commission.

COMPETENCY ASSESSMENT

It is recommended that periodic evaluation of competency utilizes results of the competency assessment to ensure testing procedures are performed consistently and accurately. Assessment activities should be conducted in a positive manner, with an emphasis on education and promoting appropriate testing practices. Staff shall be retrained if they do not meet the metrics for or fail competency assessment.

STANDARD FOR COMPETENCY ASSESSMENT FOR THE JOINT COMMISSION

JOINT COMMISSION STANDARD WT.1.30

Staff receives specific training and orientation for the tests they perform, and demonstrate satisfactory levels of competence.

RATIONALE FOR WT.1.30

For waived tests to be performed properly, the staff performing the test must be qualified to do so. Staff members who perform Waived Testing need specific training for each test performed. This training can be provided by the organization or other training programs, including other health care organizations or product manufacturers.

ELEMENTS OF PERFORMANCE FOR WT.1.30

1. Up to date competency skills of testing staff is demonstrated
2. Staff members who perform in-house laboratory tests must have adequate training for each test they are authorized to perform
3. Staff members who perform in-house laboratory tests must be oriented to the organization's specific services
4. Staff members who perform in-house laboratory tests that require the use of an instrument must be trained on the use and maintenance of that instrument
5. Competence in performing the tests is assessed according to organizational policy at defined intervals, but at least at the time of orientation
6. Competency is assessed using at least two of the following methods per person per test:
    a. Performing a test on a blind specimen
    b. Having the supervisor or qualified delegate periodically observe routine work
    c. Monitoring each user's performance of quality control
    d. Employee taking written tests specific to the method assessed
7. The director named on the CLIA Certificate of Waiver or qualified designee evaluates and documents evidence of orientation, training, and competency above

ADDITIONAL MEASURES FOR ENSURING STAFF COMPETENCY

Quality testing should be encouraged by the medical director, site director, and person overseeing testing by instructing staff to ask questions and seek help when they have concerns. Training resources should be made available to promote and ensure quality testing by all staff.

PERSONNEL TRAINING

It is essential that all testing personnel are trained and are competent in each test they perform before reporting patient results. Training must include all aspects of safety, universal precautions, and quality control. A training checklist is recommended to ensure the training process is comprehensive and documented.

TRAINING PROCESS

Training should be provided by a qualified trainer (e.g., experienced staff member, facility expert, or outside consultant) with working knowledge of test performance and laboratory practices. In addition, the trainer must have the ability to evaluate the efficacy of the training. On-the-job training should include the following:

1. The trainee reads the testing instructions
2. The trainer demonstrates the steps for performing the test
3. The trainee performs the test while the trainer observes
4. The trainer evaluates test performance; provides feedback; and additional instruction; and follow up evaluations to ensure effective training
5. The trainer administers a written knowledge assessment test
6. Both trainer and trainee document completion of training

COMPONENTS OF LAB COMPETENCY ASSESSMENT

Competency in laboratory practices shall be assessed for three phases of testing. These include:

1. Pre-analytical: Test ordering and specimen collection
2. Analytical: Control testing, test performance, and result interpretation and recording
3. Post-analytical: Result reporting, documentation, confirmatory testing, and biohazard waste disposal

CONCLUSION

CLIA Waived POCT is a valuable tool for providers in a clinical setting. It is the responsibility of the health center's administration, the provider and the staff performing the laboratory tests to ensure competency in all aspects of the testing process.

IN-HOUSE CLIA WAIVED POINT-OF-CARE DIAGNOSTIC TESTING TEMPLATES

- Implementation Worksheet
- Equipment Worksheet
- Current Procedural Terminology (CPT) Codes for CardioCheck PA Monitor and Cholestech LDX Analyzer Waived Analytes
- Lipid Testing
- CPT Codes for Siemens Vantage Waived HbA1c
- HbA1c Testing
- CardioChek Lipid Panel
- External Quality Control Schedule
- CardioChek PA Quality Control Log
- CardioChek PA Patient Log
- Patient Results Worksheet
- Laboratory Tests Orientation
- CardioChek PA Monitor Competency Assessment
- CardioChek PA Monitor Lipid Panel Written Competency Assessment
- In-House Point-of-Care Competency Form
- Lipid Profiles, Direct LDL and HbA1c Worksheet
- Cholestech LDX Lipid Panel

IMPLEMENTATION WORKSHEET

PROPOSED TESTS: LIPID PANEL, DIRECT LDL AND HbA1c **IMPLEMENTED BY:** _____

1. Current Number of CVD Patients _____
2. Current Number of CVD Patients with Diabetes _____
3. Reference Lab Charge for Lipid Panel _____
4. Reference Lab Charge for HbA1c _____
5. Reference Lab Charge for Direct LDL _____
6. Current Number of Lipid Panels Ordered Per Month _____
7. Current Number of Direct LDL Ordered Per Month _____
8. Current number of HbA1c ordered Per Month _____
9. Number of Sites in Organization _____
10. Number of Sites to Perform In-House Point-of-Care Waived Laboratory Tests _____
11. Combined Number of Lipid Panels At All Sites _____
12. Combined Number of Direct LDL At All Sites _____
13. Combined Number of HbA1c at All Sites _____
14. Combined Reference Lab Charge for Lipid Panel at All Sites _____
15. Combined Reference Lab Charge for Direct LDL at All Sites _____
16. Combined Reference Lab Charge for HbA1c at All Sites _____
17. Time Spent Calling Patients with Result _____
18. Number of Patients Who Do Not Follow through With Getting Blood Work Drawn _____

EQUIPMENT WORKSHEET

Test Name_____ New_____ Replace_____

Manufacturer_____ New_____ Replace_____

Analyzer_____ New_____ Replace_____

Location_____ Lab_____ Other_____

Adequate Ventilation_____ Yes_____ No_____

Type of Reagent_____ Number of Test per Vial/Box _____

Storage Requirement_____ Comments_____

Expiration Date_____ Comments_____

Cost per Test_____ Comments_____

Levels of Controls_____ Comments_____

Control Frequency_____ Comments_____

Storage Requirement_____ Comments_____

Expiration Date_____ Comments_____

Cost_____ Comments_____

Ancillary Supplies_____ Comments_____

Ancillary Costs_____ Comments_____

Time to Perform Test_____ Comments_____

Reference Lab Cost per Test_____ Comments_____

Reference Lab Turn Around Time_____ Comments_____

Advantages of In-House testing_____

Disadvantages of In-House testing_____

Advantages of Reference Lab_____

Disadvantages of Reference Lab_____

CPT CODES FOR CARDIOCHEK PA MONITOR AND CHOLESTECH LDX ANALYZER WAIVED ANALYTES

TEST	CARDIOCHEK PA	CHOLESTECH LDX
Lipid Panel *(Total Cholesterol, HDL, Triglycerides, Calculated LDL, Calculated Ratio)*	80061QW	80061QW
Total Cholesterol	82465QW	82465QW
HDL Cholesterol	83718QW	83718QW
Triglycerides	84478QW	84478QW
Glucose	82947QW	82947QW
Direct Measure LDL	83721QW	N/A

ESTABLISHED PATIENT E & M CODE	99211	99212	99213	99214	99215
Physician Involvement	No	Yes	Yes	Yes	Yes
Non-Physician Practitioner	Yes	Yes	Yes	Yes	Yes
Patient Problem Level	Minimal	Minor	Low to Moderate	Moderate to High	High
Usual Time Spent	5 minutes performing/ supervising services	10 minute face to face time	15 minutes face to face time	25 minutes face to face time	40 minutes face to face time
Average Medicare Reimbursement	$20	$36	$50	$79	$116

SPECIMEN COLLECTION			
G001	Medicare Claims	Venipuncture	$3.00
36415	All Other Insurance Claims	Venipuncture	Varies
36416	All Other Insurance Claims	Fingerstick	Varies

Example One

A provider orders a metabolic profile, lipid panel, and liver function tests on a patient who is just starting a statin drug.

All tests must be sent to reference lab. The lipid panel cannot be performed in-house because the lipid panel is part of the metabolic profile. The insurance carrier will only reimburse one claim from the same day.

Example Two

A patient has been on the statin drug for one month. The provider orders a follow up Lipid Panel or Direct LDL only in one month from starting statin drug. No physician visit is required.

PROCEDURE	CPT CODE	MEDICARE REIMBURSEMENT	MEDICAID REIMBURSEMENT	PRIVATE PAY REIMBURSEMENT
Non physician office visit	99211	$20.00	$20.00	Varies
Fingerstick	36416	N/A	N/A	Varies
Lipid Panel	80061QW	$18.72	$18.72	Varies
Direct LDL	83721QW	$13.33	$13.33	Varies

LIPID TESTING

Lipid testing is recognized as a means to evaluate atherosclerotic cardiovascular disease. Lipid testing may be indicated for the following conditions:

- Assessment of patients with atherosclerotic cardiovascular disease
- Evaluation of primary dyslipidemia
- Any form of co-occurring disease associated with atherosclerotic disease, or any disease leading to a formation of atherosclerotic cardiovascular disease
- Diagnostic evaluation of diseases associated with altered lipid metabolism, such as: nephritic syndrome, pancreatitis, hepatic disease, and hypo and hyperthyroidism
- Secondary dyslipidemia, including diabetes mellitus, disorders of gastrointestinal absorption, chronic liver failure
- Signs or symptoms of dyslipidemias, such as skin lesions
- As a follow up to the initial screen for coronary heart disease (total cholesterol+HDL cholesterol)—when total cholesterol is determined to be high (>240 mg/dL) or borderline-high (200-240 mg/dL), plus two or more coronary heart disease risk factors, or a HDL cholesterol (<35 mg/dL)

WHEN TO PERFORM LIPID TESTING OR DIRECT LDL

PANEL OR TEST	FREQUENCY	PURPOSE	CARDIOCHEK MONITOR TEST STRIP	CHOLESTECH LDX CASSETTE	CPT CODE CODE	MEDICARE FEE CAP
Lipid Panel (Total Cholesterol, HDL Cholesterol, Triglycerides, Calculated LDL Cholesterol)	Once per year	To monitor long term anti lipid dietary or pharmacologic therapy and following patients with borderline high total or LDL cholesterol levels	Lipid Panel	Lipid Panel	80061QW	$18.72
Lipid Panel (Total Cholesterol, HDL Cholesterol, Triglycerides, Calculated LDL Cholesterol)	Six Times per year	Marked elevations or changes to anti-lipid therapy due to inadequate initial patient response to dietary or pharmacologic therapy	Lipid Panel	Lipid Panel	80061QW	$18.72
Direct LDL	Six Times per year	Reasonable and necessary the first year for monitoring dietary or pharmacologic therapy	Direct LDL	N/A	83721QW	$13.33
Direct LDL	Three Times per year	After treatment goals have been achieved	Direct LDL	N/A	83721QW	$13.33

NOTES:

- Certain drugs may cause an increase in triglycerides.
- Routine screening and prophylactic testing for lipid disorder are not covered by Medicare. Check the requirements for private pay insured.
- It is imperative to show medical necessity by using the correct ICD-9 CM Codes

EXAMPLES OF USE OF ICD-9 CM CODES

PANEL OR TEST	FREQUENCY	PURPOSE	ICD-9 CM CODE
Lipid	Once & Six Times per Year	See Above	V58.69 Long term (current) use of other medications
Direct LDL	Three Times per year	See Above	272.8 Other disorders of Lipid Metabolism 272.9 Unspecified disorders of lipid metabolism
Direct LDL	Six Times per Year	See Above	V58.69 Long term (current) use of other medications

SCHEDULE FOR FOLLOW-UP LIPOPROTEIN ANALYSIS FOR PERSONS WHOSE LDL CHOLESTEROL LEVELS ARE BELOW GOAL LEVELS

RISK LEVEL	LDL GOAL (mg/dL)	LDL LEVEL OBSERVED (mg/dL)	REPEAT LIPOPROTEIN ANALYSIS
CVD or CVD Risks CVD Risk Equivelants	<100	<100	<1 Year
2+ Risk Factors	<130	<130	≤2 Years
0-1 Risk Factor	<160	130-159	≤2 Years
0-1 Risk Factor	<160	<130	≤5 Years

CPT CODES FOR SIEMENS VANTAGE WAIVED HbA1c

TEST	SIEMENS VANTAGE
HbA1c	83036QW

ESTABLISHED PATIENT E & M CODE	99211	99212	99213	99214	99215
Physician Involvement	No	Yes	Yes	Yes	Yes
Non-Physician Practitioner	Yes	Yes	Yes	Yes	Yes
Patient Problem Level	Minimal	Minor	Low to Moderate	Moderate to High	High
Usual Time Spent	5 minutes performing/ supervising services	10 minute face to face time	15 minutes face to face time	25 minutes face to face time	40 minutes face to face time
Average Medicare Reimbursement	$20	$36	$50	$79	$116

SPECIMEN COLLECTION			
G0001	Medicare Claims	Venipuncture	$3.00
36415	All Other Insurance Claims	Venipuncture	Varies
36416	All Other Insurance Claims	Fingerstick	Varies

EXAMPLE ONE:

A provider orders a metabolic profile, lipid panel and liver function tests on patient just starting a statin drug. The patient is also diabetic and requires a HbA1c. **All tests must be sent to reference lab. The lipid panel cannot be performed in-house because the lipid panel is part of the metabolic profile. The insurance carrier will only reimburse one claim from the same day.**

The HbA1c is not considered part of a metabolic profile. The HbA1c is a separate test. It can be performed in-house and billed separately. You cannot add the collection or office visit codes. They will be included on the metabolic profile claim.

EXAMPLE TWO:

A patient is coming to the office three days before his scheduled office visit to check his HbA1c so the provider will have the results at the time of the visit. No physician visit is required.

PROCEDURE	CPT CODE	MEDICARE REIMBURSEMENT	MEDICAID REIMBURSEMENT	PRIVATE PAY REIMBURSEMENT
Non physician office visit	99211	$20.00	$20.00	Varies
Fingerstick	36416	N/A	N/A	Varies
HbA1c	83036QW	$13.56	$13.56	Varies

GLYCOHEMOGLOBIN TESTING

HbA1c testing is a national standard used to evaluate metabolic control in diabetic patients. Please note that current American Diabetes Association guidelines recommend HbA1c testing for diagnosing Type 2 diabetes.

WHEN TO USE HbA1c

TEST	FREQUENCY	PURPOSE	SEIMENS VANTAGE	CPT CODE	MEDICARE FEE CAP
HbA1c	Every three months	Monitor metabolic control in diabetic patients	HbA1c Cartridge	83036QW	$13.56
HbA1c	Every one to two months	Treatment regimen is altered to improve control	HbA1c Cartridge	83036QW	$13.56
HbA1c	Monthly	Pregnant women	HbA1c Cartridge	83036QW	$13.56
HbA1c	As needed	Patients with uncontrolled Type 1 or Type 2, medical record documentation must support increased testing	HbA1c Cartridge	83036QW	$13.56

FREQUENTLY USED ICD-9 CM CODES FOR HbA1c TESTING

ICD-9 CODE	ICD-9 CM CODE DESCRIPTION
250.00-250.93	Diabetes Mellitus and related codes
271.4	Renal glycosuria
648.00	DM complicating pregnancy, unspecified episode
648.03	DM complicating pregnancy, antipartum complication
648.04	DM complicating pregnancy, postpartum complication
648.80	Abnormal glucose tolerance complicating pregnancy, unspecified episode
648.83	Abnormal glucose tolerance complicating pregnancy, antipartum complication
648.84	Abnormal glucose tolerance complicating pregnancy, postpartum complication
790.6	Abnormal glucose tolerance test
V58.69	Long term use of other medication

CARDIOCHEK LIPID PANEL

Purpose

The CardioChek Monitor and Lipid Panel Strips are used to monitor, treat, and manage patients with dyslipidemia at HRHCare locations. The Lipid Panel Strip measures total cholesterol, HDL cholesterol, and triglycerides. The LDL cholesterol and total cholesterol/HDL ratio are calculated from the measured analytes. A capillary blood specimen is used for the lipid measurements on the CardioChek PA monitor.

Principle

The analyzer uses reflectance photometry to measure the enzymatic reaction that occurs when a capillary blood specimen is added to the test strip. The color intensity is proportional to the concentration of the measured analytes. The darker the color in the test area of the strip indicates the higher concentration of analyte.

Equipment/Supplies

1. CardioChek PA Analyzer
2. PTS Lipid Panel Strips
3. MEMo Chip
4. Capillary Pipette for Lipid Panel Strips
5. Two AAA 1.5 volt alkaline batteries
6. Personal Protection Equipment
7. Lancet Collection Device
8. Alcohol Swabs
9. 2x2 Gauze

Reagent Storage and Stability

PTS Lipid Panel Strips

- Store test kits at room temperature, 68-86° F/20-30 °C, in a dry place in the original packaging.
- Protect from heat, direct sunlight, and humidity.
- Tightly close the bottle lid immediately after removing Test Strip.
- Use the Test Strip IMMEDIATELY after removing from the vial.
- Test kits, stored as recommended by manufacturer, are stable until the printed expiration dates on the test strip vial if the quality control is acceptable.
- Label all test kits with the date opened, date received, and opened expiration date.

PTS Multi-Chemistry Control Solutions: Level 1 and Level 2

- Store Control S solutions at room temperature, 68-86°F/20-30 °C, away from heat.
- Keep bottle tightly closed when not in use.
- Do not use if solution is cloudy.
- Do not contaminate the tip of the vial.
- Opened Control Solutions are stable for at least ten months at room temperature.
- Control Solutions, stored as recommended by manufacturer, are stable until the printed expiration dates on the Control Solution Package and Control Results are within the assayed ranges.
- Label Control Solution Vials and Package with the date opened and date received.

Check Strip

A gray Check Strip is used to verify the functionality of the CardioChek PA electronic and optic systems. The Check Strip is a permanent color standard providing a constant reading by the monitor.

Frequency for Checking Strip Performance

1. When monitor is first received
2. Each Monday when office is opened *(**Note: Perform the next day if office is closed on Monday.**)*
3. When the analyzer is dropped
4. When an unexpected result is obtained or questioned

Check Strip Performance Procedure

Equipment

1. CardioChek PA Analyzer 2. Check Strip

Running the Check Strip

1. Turn the monitor **ON**
2. ***NOTE:*** *Ensure the MEMo Chip is inserted before performing the check Strip*.
3. **RUN TEST** is shown in the display window; press the **RIGHT SIDE BUTTON** to advance the menu selections until **UTILITY** is displayed. Press the **LEFT SIDE BUTTON** to enter and accept.
4. Press the **LEFT SIDE BUTTON** when **CK STRIP** is displayed.
5. Insert the Check Strip, ribbed side up, into the Test Strip Insert Opening.
6. **PASSED** will appear in the display window if all systems and optics are acceptable.
7. Record the results and your initials on the **Check Strip Result Log.**
8. Refer to the **FAILED Performance Guidelines and Corrective Action** before testing controls or patients.
9. Press the **RIGHT SIDE BUTTON** until **EXIT** is displayed.
10. Press the **LEFT SIDE BUTTON** to enter and accept.
11. Turn off the monitor.
12. Handle the Check Strip by the base of the plastic strip.
13. Be careful not to scratch or damage the surface.

CardioChek Calibration

A MEMo chip is included in each test strip package. The MEMo Chip contains and ensures the proper settings for each test strip. The bottom of the MEMo Chip is labeled with the test name and lot number of the vial of test strips.

Purpose of the MEMo Chip

1. Tells the Analyzer which test(s) to run
2. Contains the calibration curve and the lot number code for the specific test strip lot
3. Controls test sequence and timing
4. Establishes the measuring range for each test
5. Reads the test strip expiration date

Guidelines for Using the MEMo chip

1. The MEMo Chip Port is located on top of the monitor.
2. MEMo Chip must be in place to run a test.
3. Use only the MEMo Chip that is included with each package of strips. The lot number code on the test strip vial, MEMo chip, and analyzer display must match.
4. The monitor will display EXPIRED LOT will be displayed if the expiration date in the MEMo Chip has expired.
5. Call CardioChek Polymer Technology Systems, Inc. (PTS) Customer Service for a replacement if your MEMo chip is missing or damaged.

FAILED Performance Corrective Action Guidelines

Follow the instructions below if the Check Strip fails.

Step	Action
1.	Do not perform quality control or patient tests.
2.	Clean the CardioChek PA Test Strip Insert Opening.
3.	Repeat the test with the spare Check Strip.
4.	Continue with quality control and patient testing if repeat Check Strip displays **PASS**.
5.	Call Technical Service if repeat Check Strip displays **FAIL**.
6.	Record all Troubleshooting Steps in the **Quality Control Corrective Action Log.**

Quality Control

Quality Control solutions are used to verify the performance of the entire test system; the monitor, test strips, MEMo Chip, and your technique. Two levels of Quality Control solutions; Level 1 and Level 2, are used with the CardioChek PA Monitor and Lipid Panel Strips. Each Quality Control solution has an established and expected concentration range for each analyte.

Quality Control Performance Frequency

- Run Level 1 and Level 2 Control Solution with each new lot number of PTS Lipid Strips.
- Record the lot number, control results, and initials of the person performing the test on the Quality Control Log.
- Run Level 1 and Level 2 Control Solution after a battery change.
- Run Level 1 and Level 2 Control Solution after the monitor has been dropped or damaged.

Quality Control Procedure

Equipment

- CardioChek PA Monitor
- PTS Lipid Panel Strips
- Quality Control Solutions
- Quality Control Assay Range Sheet

Running Quality Control Solutions

1. Turn the monitor **ON** *(Note: Ensure the MEMo Chip is inserted before performing the Check Strip.)*
2. **RUN TEST** is shown in the display window; press the **RIGHT SIDE BUTTON** to advance the menu selections until **UTILITY** is displayed.
3. Press the **LEFT SIDE BUTTON** to enter and accept.
4. Press the **RIGHT SIDE BUTTON** until **RUN CONTROL** is displayed.
5. Press the **LEFT SIDE BUTTON** to enter and accept.
6. Insert the Test Strip into the analyzer. ***(Note: Replace the vial cap immediately and ensure the vial is closed tightly.)***
7. **Control must be applied to the Test Strip within two minutes of removing the Test Strip from the vial.**
8. **APPLY SAMPLE** as shown in the display window.
9. Invert the Quality Control Solution bottle five times. ***(Note: Do not shake bottle.)***
10. Hold the bottle directly over and perpendicular to the white reaction area on the Test Strip.
11. Squeeze the bottle until a small drop of control solution is formed.
12. Allow the drop of control solution to fall onto the test strip. ***(Note: Do not allow the tip of the bottle to touch the test strip.)***
13. Replace the control cap.
14. Results will be displayed in two minutes.
15. Compare the results of each Control Solution to the corresponding assay range.
16. Each result must be within the specified assay range
17. Record the results with your initials and date on the PTS Lipid Panel Log Sheet if the Control Solution Results are within the control assay range.
18. Discard Test Strip as described in the HRHCare Biohazard Wastes Policy and Procedure Guidelines.
19. Perform Level 2 Quality Control in the same manner.
20. Patient testing may be performed if both levels of control are within assay range.
21. Refer to the **Quality Control Corrective Action** for instructions if either control falls outside the assay range.

Quality Control Corrective Action

Follow the instructions below if any level of the Control Solutions are not within the assay ranges.

Step	**Action**
1.	Do not report patient results.
2.	Review the quality control procedure.
3.	Ensure you are using Multi - Chemistry Control Solutions.
4.	Ensure Multi-Chemistry Control Solutions and PTS Lipid Panel Test Strips are not outside the expiration and discard dates.
5.	Check the room temperature of the testing location.
6.	Repeat test using a new Test Strip and Control Solution.
7.	If result is still outside the assay range, call PTS Technical Service.
8.	Record all Troubleshooting Steps in the **Quality Control Corrective Action Log.**

Lipid Panel Test Procedure

Universal Precautions and Personal Protection Equipment must be followed and used respectively when handling and collecting blood specimens. A fresh fingerstick specimen will be obtained for testing glucose on the CardioChek PA Monitor and PTS Lipid Panel Test Strips.

1. Review the lab requisition form for patient name, date of birth, current date, provider name, and test requested.
2. Ask patients to identify themselves by names and dates of birth.
3. Remove Test Strip from the vial.
4. Put on gloves.
5. Check fingers for wounds, bruising, and warmth.
6. Ask patient to run warm water over their hands if the fingers are cold to the touch. The warm water will help to warm the fingers and facilitate better blood flow to the fingers.
7. Select a finger that is free of wounds or bruising.
8. Ask patient if there is a particular finger they prefer.
9. Cleanse the site to be punctured on the finger with an alcohol swab.
10. Allow the area to dry completely. ***Note: The presence of alcohol on the puncture site can cause inaccurate results.***
11. Press the single use auto – lancet device firmly against the cleansed site and push button to release. A small round drop of blood will form. ***Do not milk the finger.***
12. Wipe away the first drop of blood.
13. Collect the blood in the collection pipette.
14. Turn the Monitor **ON**. ***(Note: Press either the LEFT or RIGHT SIDE BUTTON.)***
15. Insert the Test Strip when **INSERT STRIP** is shown on the display window.
16. **APPLY SAMPLE** as shown on the display window.
17. Hold the collection pipette directly over and perpendicular to the white test area on the strip.
18. Push the plunger until the blood specimen is expelled from the pipette.
19. Test results will be displayed within two minutes.
21. Record the test results on the **Patient Test Log** along with your initials and date.
21. Results outside the measuring range for any analyte are to be confirmed with a serum sample sent to the reference laboratory.
22. Notify the provider if the results are outside the measuring range.

FINGERSTICK LIPID PANEL NORMAL RANGES	
Total Cholesterol:	Below 200 mg/dL
HDL Cholesterol:	Greater than 60 mg/dL
Triglycerides:	Below 150 mg/dL
LDL Cholesterol:	Below 100 mg/dL

CONFIRMATION LEVELS SENT TO REFERENCE LABORATORY
"Low" Display
"High" Display
N/A for Any Analyte

MEASURING RANGE	
Total Cholesterol:	100 mg/dL-400 mg/dL
HDL Cholesterol:	15-100 mg/dL
Triglycerides:	15-500 mg/dL

Instrument Maintenance

Cleaning

1. Wash hands and dry thoroughly before handling to keep the meter and test strips free of oils and other contaminants.
2. Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.
3. Avoid exposing meter and test strip to excessive humidity, heat, cold, dust, or dirt.
4. Store the monitor at room temperature (68 - 86˚F, 20 - 30˚C).
5. Store the monitor at 20 - 34% relative humidity.
6. The exterior of the meter can be cleaned using a moist (not wet) lint-free tissue with a mild detergent or disinfectant solution. Wipe dry with lint free tissue after cleaning. Do not allow solution to run down or in around the buttons. This may cause a malfunction.
7. Wipe the Test Strip Insert Opening with a clean, damp (not wet) lint free tissue or cloth. Ensure the glass is clean with no dust or fingerprints. The glass must be completely dry before running a test.
8. Clean the meter daily or when soiling is observed.
9. Record the cleaning on the Maintenance Log.
10. Store meter in case whenever possible.

Changing the Battery

1. Replace batteries when the monitor display reads CHANGE BATTERY. No more tests can be performed until the batteries are changed.
2. Press firmly on the battery cover and slide the cover in the direction of the MEMo Chip port.
3. Remove the old batteries from the compartment and safely discard.
4. Insert the new batteries into the battery compartment with the (+) terminal facing to the left on the top battery, and to the right on the bottom battery as marked.
5. Replace the battery door.
6. Turn the monitor ON to ensure batteries are correctly installed.
7. Record battery replacement on the Maintenance Log.

Limitations of Procedure

1. Dopamine and methyldopa decrease the results of all the lipid tests.
2. Extremely high doses of ascorbic acid (Vitamin C) decrease the results of all lipid tests.
3. Hematocrit readings in the range of 30% - 45% does not significantly affect normal glucose ranges.
4. Cosmetics such as handcreams or lotions often contain glycerol. Use of these products may cause inaccurate results.

Sources

1. CardioChek PA User Guide, Polymer Technology Systems, Inc.
2. PTS Lipid Panel Strips, product insert, Polymer Technology Systems, Inc.
3. Multi-Chemistry Control Solutions, product insert, Polymer Technology Systems, Inc.

EXTERNAL QUALITY CONTROL SCHEDULE

ANALYTE	DEVICE OR KIT	LEVELS OF CONTROL	FREQUENCY	OPTICS CHECK FREQUENCY	DOCUMENTATION
Glucose	Bayer Ascensia	Three	Each Monday	N/A	Log book with date and initials. Document out of range follow up
Total Cholesterol, Triglyceride	Cardio ChekPA	Two	New shipment and lot number change	Daily	Log book with date and initials. Document out of range follow up
HDL	Cardio ChekPA	Two	New shipment and lot number change	Daily	Log book with date and initials. Document out of range follow up
HbA1c	Vantage	Two	New shipment and lot number change	Monthly	Log book with date and initials. Document out of range follow up
Microalbuminurua /Creatinine	Vantage	Two	New shipment and lot number change	Monthly	Log book with date and initials. Document out of range follow up
Urinalysis	Status	Two	New bottle of strips opened	N/A	Log book with date and initials. Document out of range follow up
INR	HemoSense	Two	Onboard Controls with every patient test	N/A	Log book with date and initials. Document out of range follow up
Hgb	HemoCue	Three	New shipment and lot number change	Internal	Log book with date and initials. Document out of range follow up
Lead	LeadCare II	Two	Each New Kit	Weekly	Log book with date and initials. Document out of range follow up
Strep A	OSOM	Two	Each New Kit	N/A	Log book with date and initials. Document out of range follow up
Pregnancy	OSOM	Three	Each New Kit	N/A	Log book with date and initials. Document out of range follow up

Perform controls anytime patient results are questioned by the provider.

CardioChek PA QUALITY CONTROL LOG

QUALITY CONTROL LEVEL 1 LOT #:		EXP. DATE:
LEVEL 1 EXPECTED RANGES		
Total Cholesterol	Triglycerides	

QUALITY CONTROL LEVEL 2 LOT #:		EXP. DATE:
LEVEL 2 EXPECTED RANGE		
Total Cholesterol	Triglycerides	

QUALITY CONTROL LEVEL 1 LOT #:	EXP. DATE:
LEVEL 1 EXPECTED RANGE	
HDL CHOLESTEROL	

QUALITY CONTROL LEVEL 2 LOT #:	EXP. DATE:
LEVEL 2 EXPECTED RANGE	
HDL CHOLESTEROL	

CardioChek SN	STRIP LOT #	EXP. DATE	TOTAL CHOLESTEROL		TRYGLYCERIDES		LDL CHOLESTEROL		HDL CHOLESTEROL		ACCEPT	INITIALS	DATE
			LEVEL 1	LEVEL 2	LEVEL 1	LEVEL 2	LEVEL 1	LEVEL 2	LEVEL 1	LEVEL 2			

CardioChek PA Patient Log

CardioChek PA SN: _____

DATE	MEDICAL RECORD NUMBER	DATE OF BIRTH	STRIP LOT #	TOTAL CHOLESTEROL <200 mg/dL	HDL >50 mg/dL	TRIGLYCERIDES <150 mg/dL	LDL >100 mg/dL	TOTAL CHOLESTEROL/HDL <3.5	COMMENTS	INITIALS

PATIENT RESULTS WORKSHEET

PATIENT NAME: _____ **MEDICAL RECORD NUMBER:**_____

DOB: _____ **PCP:**_____

DATE	LIPID PANEL					HbA1c	GLUCOSE	COMMENTS	INITIALS
	TOTAL CHOLESTEROL <200 mg/dL	HDL >50 mg/dL	TRIGLYERIDES <150 mg/dL	HDL <100 mg/dL	TOTAL CHOLESTEROL/ HDL <3.5	<7.0%	FASTING <100 mg/dL		

LABORATORY TESTS ORIENTATION

EMPLOYEE NAME/TITLE: _____

DEPARTMENT: _____ **START DATE:** _____

Orientation, Knowledge, and Skills Assessments needs to be reviewed and completed within 90 days of work assignment. A passing score of 100% must be achieved for new and established employees.

Discuss Joint Commission and NYSDOH Regulatory Compliance and Standards	Skills Assessment for Performing and Documenting All Levels of QC for Ascensia Glucose, Vantage HbA1c, and CardioChek PA Monitor or Cholestech LDX Analyzer
Discuss Health Center In-House Point-of-Care Laboratory Policies and Procedures	Discuss Failed QC Follow Up and Documentation
Review In-House POCT, Quality Control, and Maintenance Policy and Procedure Manual	Skills Assessment for Performing and Collecting a Fingerstick Specimen
Discuss When In-House POCT Laboratory Tests Will be Performed and When a Laboratory Test Requisition is Sent to a Reference Laboratory	Skills Assessment for Performing a Patient Specimen on the Ascensia Contour Glucose Meter, Vantage HbA1c Analyzer, and CardioChek PA Monitor or Cholestech LDX
Discuss In-House POCT Laboratory Tests and New Staff Experience with POCT	Skills Assessment for Recognizing Invalid Patient Results and Follow Up Documentation Protocol
Discuss Storage and Temperature Requirements for In-House POCT Laboratory Tests QC Materials and Glucose, HbA1c, and Lipid Reagents	Skills Assessment for Documenting Patient Results on Log Sheet and in Patient Chart
Discuss QC Performance Frequency and Documentation for All In-House POCT Laboratory Tests	Skills Assessment for Documenting Patient Results in Electronic Medical Record (EMR)
Discuss Proper Fingerstick Specimen Collection	Discuss Critical Values Follow Up Protocol
Discuss Specimen Volume Required for Ascensia Contour Glucose, Vantage HbA1c, and CardioChek PA Monitor or Cholestech LDX Lipid Analyzer	Knowledge Assessment Written Tests for Ascensia Contour Glucose, Vantage HbA1c, CardioChek PA Monitor or Cholestech LDX

Observed performance and authorization to perform certain tasks may be delayed until after initial orientation. Document the reason for the delay in clearing employee to perform In-House Point-of-Care Laboratory Tests.

PROCEDURE	DATE AND INITIALS ORIENTATION APPROVED	DATE AND INITIALS THREE MONTHS APPROVED	DATE AND INITIALS SIX MONTHS APPROVED
Bayer Ascensia Glucose Meter			
Siemens HbA1c			
CardioChek PA Lipid Monitor or Cholestech LDX			
Fingerstick			

CardioChek PA Monitor Competency Assessment

NAME: _____ **DATE:** _____

LOCATION: _____ **TITLE:** _____

NURSE MANAGER: _____

REVIEWED BY: _____ **DATE:** _____

INTRODUCTION AND SET UP

1.	Locates and describes the function of the following: Display ENTER Button NEXT Button Test Strip Insert Opening MEMo Chip Port	Met	Not Met
2.	Successfully installs the MEMo Chip	Met	Not Met
3.	Locates batteries and identifies correct batteries to be used Correctly installs batteries	Met	Not Met

CHECKING THE SYSTEM

4.	Identifies and describes the function of the Check Strip Explains when to analyze the Check Strip Successfully performs the Check Strip Explains troubleshooting procedure for failed Check Strip	Met	Not Met
5.	Successfully installs the MEMo Chip	Met	Not Met
6.	Locates batteries and identifies correct batteries to be used Correctly installs batteriest	Met	Not Me

EXTERNAL QUALITY CONTROL

7.	Identifies and describes the function of performing external controls for total cholesterol and triglycerides Explains when to performs two levels of controls Successfully performs two levels of controls for total cholesterol and triglycerides Explains troubleshooting procedure for failed external controls	Met	Not Met
8.	Identifies and describes the function of performing external controls for HDL Explains when to perform two levels of controls Successfully performs two levels of controls for HDL Explains troubleshooting procedure for failed external control	Met	Not Met

FINGERSTICK AND PATIENT TESTING

9.	Assembles all supplies needed for patient fingerstick testing	Met	Not Met
10.	Performs successful fingerstick		
11.	Sample placed properly on strip	Met	Not Met
12.	Strip placed properly in drawer and with correct time frame	Met	Not Met
13.	Compare fingerstick results with venous draw Results are within acceptable % bias Two comparisons are to be performed on two different patients, both results must be within acceptable % bias	Met	Not Met

CardioChek PA Monitor Lipid Panel Written Competency Assessment

NAME: _____ **DATE:** _____

TITLE: _____ **LOCATION:** _____

1. What tests are measured on the Lipid Panel Strip?

2. What are the storage requirements for the Lipid Panel Strip?

3. When is the Optics Strip performed?

4. What are the storage requirements for the Optics Strip?

5. How many levels of controls are required for the Lipid Panel Strip?

6. What is the frequency of performing controls? When should controls be performed?

7. What procedures should be followed for out of range controls?

8. What is the measuring range for total cholesterol, HDL cholesterol, and triglycerides?

9. What are the calculated tests on the Lipid Panel Strip?

NAME: _____ **DATE:** _____

10. List reasons for LDL cholesterol not being calculated?

11. What is the sample volume for performing the Lipid Panel?

12. What is the collection device for the Lipid Panel?

13. List reasons for a short sample?

14. What is the follow up procedure for a short sample?

15. List reasons for falsely elevated triglycerides?

16. What analyte is affected by excessive squeezing of the finger?

17. How can a short sample be detected?

18. What does “LO” indicate on the display screen?

19. What does “HIGH” indicate on the display screen?

20. Where is the patient and control results documented?

IN-HOUSE POINT-OF-CARE COMPETENCY CHECKLIST

DATE: _____

EMPLOYEE NAME: _____ **TITLE:** _____

ASSIGNED LOCATION: _____ **PRECEPTOR:** _____

LIPID PANEL: PTS CARDIOCHEK	**INITIALS**
Competency Assessment: 1. Read entire Policy/Procedure. 2. Complete and pass written test (passing criteria is 100%). 3. Direct observation by preceptor (return demonstration, complete).	
PRECEPTOR OBSERVES	
1. Performs routine test by fingerstick.	
2. Verifies test strips and QC solution current.	
3. Performs one level of control.	
4. States when quality control is performed.	
5. Documents results in log book and EMR.	
6. Documents observation.	
CRITICAL POINTS	
a. **Sample Collection:** All trained staff collect fingerstick specimens.	
b. **Patient and Operator Identification and Documentation:** Enters patient and operator identification correctly on patient log and EMR.	
c. **Quality Controls:** Two levels are performed with each new shipment and lot number. Controls are stored at room temperature.	
d. **Storage Requirements:** Strips are stored at room temperature.	
CRITICAL RESULTS	
a. **Sample Collection:** Must allow alcohol to dry prior to fingerstick. **PASS:** _____ **FAIL:**_____ **VALIDATOR:** _____	

LIPID PROFILES, DIRECT LDL AND HbA1C WORKSHEET

Scenario One

A patient has a 1:00 pm appointment. Upon review of the chart, you discovered that he has not had a recheck of his LDL. You bring this to the provider's attention. The provider wants that LDL. The patient was not instructed to be fasting. It is now 12:45 pm. What can you do?

TEST	MONITOR/ANALYZER	CPT CODE

Scenario Two

Your 8:30 am patient is having his Lipid Panel and HbA1c performed when instructed. Upon review of the chart, it is noted that he has not had the Lipid Panel and HbA1c performed in six months. The patient arrives and explains that he did not eat breakfast. What can you do?

TEST	MONITOR/ANALYZER	CPT CODE

Scenrio Three

Develop one for your health center and solve.

TEST	MONITOR/ANALYZER	CPT CODE

CHOLESTECH LDX LIPID PANEL

PURPOSE

The Health Center shall perform fingerstick whole blood lipid profiles on patients to monitor and treat hyperlipidemia. The lipid panels consist of total cholesterol, HDL cholesterol, triglycerides, calculated LDL cholesterol, and total cholesterol/HDL ratio. The lipid panel shall be performed on the Cholestech LDX Analyzer. The Cholestech LDX Analyzer is CLIA Waived. The provider and patient review and discuss lipid profile results at the time of the patient visit. The ability to test patients at the time of the visit ensures that patients are compliant in their prescribed treatment plan and medications.

ENVIRONMENTAL REQUIREMENTS

STORAGE REQUIREMENTS

1. Temperature between 20°C to 31°C (68° to 87°F)
2. Stable work surface
3. No direct heat (oven or room heater)
4. No bright light (sunlight or a spot light)

**Note: If the temperature or light requirements are not acceptable, the Analyzer will shut down until they are met*

ELECTRICAL REQUIREMENTS

1. Grounded wall outlet supplying 100 to 240 VAC with each power supply
2. Two electrical outlets (one for printer and one for analyzer)

*** Note: A surge protector may be used in the event a grounded wall outlet is not available*

QUALITY CONTROL LEVELS 1 AND 2

1. Refrigerate and store Quality Control materials at 2° to 10°C (36° to 46°F).

TEST CASSETTES

1. Refrigerate and store test cassettes at 2° to 8°C (36° to 46°F).
2. Cassettes remain in foil pouch until ready for use.

ROUTINE CLEANING

Cleaning the Outside of the LDX Analyzer

1. Dampen a clean, non - abrasive cloth with a solution of 70% isopropyl alcohol, or 5% bleach, or any non-staining, commercially available disinfectant.
2. Record date on Routine Cleaning Log.

Cleaning the Cassette Drawer of the LDX Analyzer

1. Moisten a cotton swab with water, or 70% isopropyl alcohol solution, or 5% bleach and apply to the cassette drawer.
2. Dry cassette drawer with a clean and dry cotton swab.
3. Record Date on Routine Cleaning Log.

MAINTENANCE

No maintenance is required other than routine cleaning as needed. All maintenance shall be performed at Cholestech Headquarters in Hayward, California. Contact Cholestech Technical Services at 1-800-733-0404, to arrange shipment of the malfunctioning LDX Analyzer to California. Record all troubleshooting steps and the malfunction of the LDX Analyzer on the troubleshooting log.

CALIBRATION

No calibration is required or performed by the user. Test information is on the brown magnetic stripe of the cassette. The Cholestech LDX reads the brown magnetic stripe each time a test is performed on the cassette to confirm the cassette is calibrated.

CALIBRATION VERIFICATION

Assayed calibration verification material is designed for verifying the reportable range of tests on the Cholestech LDX System. The material is assayed for total cholesterol, HDL cholesterol, triglycerides, and Glucose Cholestech LDX cassettes.

SPECIMEN TYPE, COLLECTION, HANDLING, AND REJECTION

Specimen Type

1. Fingerstick whole blood sample
2. Required sample volume is 35 mcg

Collection and Handling

1. Perform a fingerstick to obtain whole blood sample.
2. Collect sample in the 35 mcg capillary pipette.
3. Sample is stable for 5 minutes in the 35 mcg capillary tube.

Specimen Rejection

1. Discard the 35 mcg capillary pipette if any air bubbles are present and collect specimen in another 35 mcg capillary pipette.
2. Perform another fingerstick if sample collection takes longer than 30 seconds.
3. Only fingerstick whole blood samples may be used for measuring a lipid profile on the Cholestech LDX Analyzer.

Optics Check Cassette

The Optics Check Cassette is used to test and check the electronics of the LDX Analyzer. Proper voltage in each test window is required to ensure the LDX Analyzer is performing optimally and providing accurate patient results

Storage and Handling

1. Store in the case provided
2. Store at room temperature

*** Note: Do not use a damaged or expired Optics Check Cassette. Do not touch the reaction bar or allow it to become wet; dirty, or scratched.*

FREQUENCY FOR TESTING THE MACHINE

1. Once each day before testing patient samples
2. After the Cholestech LDX System has been moved or serviced
3. Retain the print out of results each time the Optics Check is performed

Required Materials

1. Optics Check Cassette
2. LDX Analyzer
3. Optics Check Quality Control Log

Specimen Preparation

1. No sample is required for testing

Optics Check Cassette Procedure

1. Press the RUN button. After verifying the "**SELF TEST OK**" message, the drawer will open and display on the screen **LOAD CASSETTE AND PRESS RUN.**
2. Place the Optics Check Cassette into the cassette drawer.
   ***Note: Do not place any blood or control sample on the Optics Check Cassette*
3. Press the RUN button again and the Analyzer will automatically close the drawer to perform the Optics Check.
4. The display screen and print out will appear as the example below. The four numbers represent each optical channel in the Analyzer.

Example Only: Optics Check
Date: 00-00-00
Time: 00:00
99-99-99-99

5. All four channels on the Optics Check Cassette must read between 80-105. Results will appear on the print out.
6. Record your initials on the print out.
7. Place the print out in Optics Check Quality Control Log.

OPTICS CHECK CASSETTE PROCEDURE

**Note: If any channel does not read between 80-105, the Analyzer will shut down and the screen and printout will display "Optics Check Failure."

Out of Range Optics Check Results Procedure

1. Repeat the Optics Check Cassette. The Analyzer may be used for patient testing if the results on all four channels are between 80 - 105.
2. Record troubleshooting steps on the Optics Check Quality Control Log.
3. Place the print out in the Optics Check Quality Control Log.
4. If the Optics Check Cassette is still out of range, use a new Optics Check Cassette.
   ***Note: Do not use any liquid to clean the Optics Check Cassette test windows. Do not apply any liquid or dry substance to the test windows.*
5. If the new Optics Check is still out of range, contact Cholestech Technical Services, 1-800-733-0404.
6. Record all steps and results when troubleshooting out of range Optics Check results.

LEVEL ONE AND LEVEL TWO QUALITY CONTROL PROCEDURE

Reagents

1. The controls are prepared from human constituents in an aqueous preservative medium containing antimicrobial agents.

Precautions

1. For in vitro use only
2. All human source material used in the manufacturing of the control materials was nonreactive to Hepatitis and Human Immunodeficiency Virus using techniques specified by the U.S. Food and Drug Administration. No known method can ensure complete absence of human pathogens, use this product using the appropriate precautions.
3. ALWAYS wear gloves when handling and performing the Quality Control Procedure.

QUALITY CONTROL LEVEL ONE AND LEVEL TWO PROCEDURE

1. Discard this product with infectious medical waste. Do not discard in general waste.
2. This product is supplied ready for use. Any tampering with the control materials will invalidate any diagnostic use of the product.
3. Do not use this product for instrument calibration.

Storage and Stability

1. Store Cholestech LDX Controls upright in the refrigerator at 2° to 10°C (36° to 50°F). Unopened vials stored under these conditions are expected to give stable results through the expiration date of the package.
2. Once the controls are opened, the controls are good for thirty days when refrigerated at the required temperature. Place the opened date of the control vials. Discard the opened control vials after thirty days.
3. Minimize exposure to strong light.
4. **DO NOT FREEZE.**
5. Discard control vials that are out of date and not in use in a biohazard container.

Frequency of Testing Level One and level Two Quality Controls

1. Test both levels of controls each time a new shipment and lot number of cassettes are received.
2. Test both levels of controls when performing Proficiency Testing events.
3. Test both levels of controls if patient test results are questioned.

Materials Required

1. Cholestech LDX Analyzer and power supply
2. Cholestech LDX Cassettes
3. Latex or non-latex gloves
4. Biohazardous waste containers
5. Cholestech Level One and Level Two Quality Control Material
6. Cholestech Mini-Pet Pipette
7. Cholestech pipette tips

Performing Level One and Level Two Quality Control

1. Remove one vial each of Level One and Level Two Quality Control from the refrigerator.
2. Remove two LDX cassettes from the refrigerator.
3. Allow controls and cassettes to come to room temperature for ten minutes.
4. Verify that the control number on the control vials are the same as the control assay sheet.
5. Put on gloves.
6. Press **RUN** to open the cassette drawer.
7. Open the foil pouch and remove the cassette. Do not touch the reaction bar or the brown magnetic stripe.
8. Place the cassette in the drawer.
9. Securely place a tip on the Mini-Pet.
10. Invert the quality control vial 8-10 times. Do not shake the vial.
11. Remove the cap from Level One control vial.
12. Push down the plunger of the Pipette until it stops.
13. Place the tip to the bottom of the quality control vial keeping the plunger down.
14. Release the plunger allowing the control material to flow into the pipette tip. (The pipette is calibrated to aspirate and dispense the correct amount of control sample.)
15. Place the pipette tip inside the test well.
16. Push the plunger down forcing the control material into the test well. Allow all the control material to go into the test well.
17. Press **RUN**. The drawer will close to begin the testing process.
18. Place everything that has touched the control material in a biohazard waste container.
19. The Analyzer will beep after five minutes to indicate the testing process is complete and the drawer will automatically open.
20. The measured analytes will appear on the screen and print out.
21. Compare the control results with the control assay range sheet to ensure that the control results are acceptable.
22. Remove the cassette and place in a biohazard container. Do not leave a used or new cassette in the drawer.
23. Press **STOP** to close the drawer.
24. Record your initials on the print out.
25. Place the label on the Quality Control Log.
26. Repeat the steps to test Level Two Quality Control.

Out of Range Quality Control Results Procedure

1. Patients cannot be analyzed unless both levels of quality control are within the assay range.
2. Check the expiration date for the test cassette and quality control materials.
3. Verify the lot number on the control vial and the assay sheet are the same.
4. Retest the control level that is out of range using a new sample from the control vial.
5. Pay close attention to possible errors in technique.
6. Patient samples may be tested if both levels of control are within the assayed limits.
7. Retest with a control sample from a new quality control vial.
8. Test patients if the control is within the assay range.
9. Call Cholestech Technical Services at, 1-800-733-0404, if the controls are still out of range.
10. Patients cannot be tested until the problem is resolved.

FINGERSTICK SPECIMEN COLLECTION AND HANDLING

Materials Required

1. Latex or non latex gloves
2. Alcohol swabs
3. Gauze or cotton balls
4. Lancets
5. Cholestech 35 mcg Capillary Tubes
6. Cholestech Capillary Plungers
7. Band-Aids
8. Biohazard sharps container

Specimen Collection

1. Allow test cassettes to come to room temperature for ten minutes.
2. Ensure patient's hand is warm. Ask patient to run their hands under warm water to warm their hands and encourage a good blood flow.
3. Ask the patient their name and birth date to verify information on their encounter form.
4. Ask the patient if they have been fasting and for how long.
5. Consult with the provider if the patient is not fasting before continuing the specimen collection.
6. Put on latex or non latex gloves.
7. Assemble the capillary pipette and plunger. Place to the side.
8. Choose a site on the side of either the ring or middle finger. Make sure the selected finger is warm to the touch and free of any open wounds.
9. Clean the selected site with an alcohol swab. **Dry the finger thoroughly before performing the fingerstick. Alcohol mixed with blood will hemolyze the specimen and falsely lower the total cholesterol.**

   ***Note: Heavy creams or lotions left on the finger will falsely elevate triglycerides.*
10. Place the lancet device firmly against the cleansed site and firmly press the lancet trigger to puncture skin.
11. Squeeze the finger gently to obtain a large drop of blood.
12. Wipe away the first drop as it may contain tissue fluid.
13. Squeeze the finger gently until a blood drop forms.

    *** Note: Do not milk the finger. The puncture site should provide a free - flowing drop of blood.*
14. Hold the assembled capillary pipette and plunger horizontal to the puncture site.
15. Touch the pipette to the drop of blood without touching the skin. The capillary pipette will fill by capillary action to the black mark on the capillary pipette. ***Do not collect air bubbles*. If an air bubble occurs, discard the capillary pipette and collect specimen in a newly assembled capillary pipette and plunger.**

FINGERSTICK SPECIMEN COLLECTION AND HANDLING

1. Fill the 35 mcg capillary pipette within ten seconds. **D**elay in filling the capillary pipette can cause clotting and contain tissue fluids that give erroneous results.**
2. **Proceed to "Patient Test Procedure" immediately.**
3. ****Place blood sample in the cassette before proceeding to steps 18 and 19.*
4. Place a dry gauze on the puncture site and ask the participant to apply pressure to stop the bleeding.
5. Apply a band aid to the puncture site.

PATIENT TEST PROCEDURE

Materials Required

1. Latex and non latex gloves
2. Cholestech LDX Analyzer and power supply
3. Cholestech LDX Test Cassette
4. Fingerstick whole blood filled capillary pipette with plunger

Running a Test

1. Press RUN to open the test drawer.
2. Open the foil pouch and remove the test cassette. (Remove the desiccant pack from the test cassette. ***Do not touch the reaction bar or the brown magnetic stripe.***)
3. Place the cassette in the test drawer. ***Do not touch the mag stripe area or the reaction bar.***
4. Place the filled 35 mcg pipette with plunger in the test well in the appropriate position.
5. Push the plunger down forcing the blood into the test well. Allow the entire sample to go into the test well.
6. Press **RUN** to close the test drawer and begin the testing process.
7. The drawer will automatically open at the end of the five minute testing process.
8. The test results will appear on the print out.
9. If the printer fails, the results will appear on the screen. Press the **DATA** button to review and record all the test results.
10. Place the patient's print out in the appropriate location on the chart for the provider's review.
11. Document your initials on the print out.
12. If the results are outside the manufacturing range, a > or < will appear on the screen.
13. Discard all items used in the testing process in the proper biohazard containers.
14. Consult with the provider if the results are outside the patient range and/or the LDX Analyzer measuring range to determine if a venous draw will be sent to the lab for confirmatory results. Results requiring consultation are as follows:
    a. Triglycerides < 45 or > 400 mg/dL
    b. Total Cholesterol < 100 or > 500mg/dL
    c. HDL Cholesterol < 15 or > 100 mg/dL
    d. Any analyte displaying "N/AU as a result
15. If there is a malfunction with the Analyzer, an error message will be displayed.
    ***Note: Call Cholestech Technical Services at 1-800-733-0404 if an instrument malfunction occurs.*
16. Remove the cassette and place in a biohazard waste container.
17. The drawer should be empty when not in use.
18. Press **STOP** to close the drawer.

PATIENT RANGES

Cholesterol	Less than 200 mg/dL
HDL Cholesterol	**Women:** Greater than 60 mg/dL **Men:** Greater than 50 mg/dL
Triglycerides	Less than 150 mg/dL fasting
Calculated LDL cholesterol for patients not being treated for diabetes and cardiovascular disease	Less than 130 mg/dL
Calculated LDL cholesterol for patients being treated for Diabetes and cardiovascular disease	Less than 100 mg/dL

CHOLESTECH LDX ANALYZER MEASURING RANGE

Total Cholesterol	100-500 mg/dL
HDL Cholesterol	15-100 mg/dL
Triglycerides	45-650 mg/dL

CALCULATED ANALYTES

LDL Cholesterol	Friedwald Equation: Total Cholesterol-HDL-(Triglycerides/5)
Total Cholesterol/HDL Ratio	Total Cholesterol/HDL

LIMITATIONS

1. Triglycerides > 400 mg/dL: estimated LDL will not be calculated.
2. Total cholesterol, HDL cholesterol, and triglycerides outside the measuring range will report the LDL as N/A.
3. Triglycerides >650 mg/dL may interfere with measurement of the HDL and HDL results will appear as N/A.

COMMON ERROR MESSAGES

Message	Possible Cause
RDNO (Reaction Did Not Occur)	• Sample clotted due to a prolonged fingerstick • Air bubbles in the capillary pipette • Cassette malfunction
Mag Stripe Error	• Scratched mag stripe • Dirty mag stripe
Used Cassette	• Blood outside of the well on the cassette • Cassette malfunction

Sources:

- Cholestech LDX Manufacturer Procedure Manual

REFERENCES

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